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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/909,715

07/20/2001

Brian J. Cox

MCRVT-057A

1492

37374

7590

11/10/2008

INSKEEP INTELLECTUAL PROPERTY GROUP, INC  
2281 W. 190TH STREET  
SUITE 200  
TORRANCE, CA 90504

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

11/10/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

inskeepstaff@inskeeplaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/909,715	<b>Applicant(s)</b> COX, BRIAN J.	
	<b>Examiner</b> Darwin P. Erez	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44-47, 54-56, 59-61 and 64-100 is/are pending in the application.
- 4a) Of the above claim(s) 44-47, 54-56, 59-61, 64-80 and 86-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 81-85 and 95-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This Office action is in response to applicant's communication filed on 7/31/08.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 81-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,234,456 to Silvestrini in view of US 5,258,042 to Mehta.

(claim 81) Silvestrini discloses a method comprising the steps off :

providing an implant comprising an expandable stent **40** having fenestrations, said expandable stent comprising a substantially cylindrical body member located between two ends and defining a lumen therein (Fig. 3); wherein blood is capable of flowing through the fenestration; said stent having a reactive material selective applied to not all of the fenestrations of the support device (only fibers **26** are filled with the reactive material; col. 3, ll. 48-52);

delivering the stent to the vascular system of a patient (blood vessel);  
supporting the blood vessel with the stent;  
permitting blood to flow through the stent (col. 2, ll. 48-63); and  
activating the reactive material to expand fibers **26**, which will inherently reduce flow through the fenestrations since the expanded fiber will reduce the size of the openings;

Silvestrini is silent with regards to using the stent to treat a vascular aneurysm.

However, Mehta discloses another implant comprising a stent, wherein the stent has a reactive material (hydrogel, see abstract), and wherein the stent is used to treat a vascular aneurysm (see Fig. 2). The stent of Mehta expands once the reactive hydrogel is activated to reduce/limit the flow of blood to the aneurysm.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Silvestrini to include the step of using the device to treat a vascular aneurysm because Mehta discloses that it is well known in the art to use a stent having a reactive material to treat an aneurysm by reducing/limiting the flow of blood to the aneurysm. The stent of Silvestrini will also provide structural support in the weakened area.

Furthermore, one of ordinary skill in the art would have found it obvious to try and use the device of Silvestrini in treating an aneurysm because Silvestrini discloses a stent having an expandable reactive material that is capable of reducing the flow of blood through an opening in the device. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).`

(claim 82) The hydrophilic material is reactive to tissue fluids, which has a pH value of around 7.4.

(claim 83) The reactive material is a hydrogel that volumetrically expands.

(claims 84 and 85) The stent is delivered by a catheter (col. 2, ll. 48-51).

Silvestrini is silent with regards to the use of balloon catheter to deliver the stent.

However, the examiner takes Official notice that the use of balloon catheters to deliver stents are well known in the art and would be obvious to one of ordinary skill in the art.

5. Claims 95-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini in view of Mehta, as applied to the rejections above, and in further view of US 6,090,911 to Petka et al.

(claim 95) The above combination of Silvestrini/Mehta, as recited in the rejection to claim 81) except for the hydrogel having a first state of protonation and a second state of protonation. However, Petka discloses that hydrogels belongs to a class of functional materials that respond to a variety of stimuli, such as swelling in the device of Silvestrini, or protonation of the acidic group in certain pH level (col. 9, ll. 28-43).

Therefore, one of ordinary skill in the art would have found it obvious to use any known hydrogels in the device of Silvestrini/Mehta, including the hydrogels disclosed by Petka, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

(claim 96) The hydrophilic material is reactive to tissue fluids, which has a pH value of around 7.4.

(claim 97) The reactive material is a hydrogel that volumetrically expands.

(claims 98-100) Petka discloses various hydrogels having ethylenically unsaturated monomer with an ionizable functional group of either an amine or carboxylic acid (col. 9, ll. 63 - col. 10, ll. 19; col. 9, ll. 44).

### ***Response to Arguments***

6. Applicant's arguments filed 7/31/08 have been fully considered but they are not persuasive.

The applicant argued the examiner's statement that it would be inherent for the hydrophilic material within the hollow fibers of Silvestrini to reduce flow through the openings between adjacent fibers. It was argued that the device of Silvestrini merely expands to increase the overall diameter of the device.

The examiner agrees that the device of Silvestrini expands to increase the overall diameter of the device. This is accomplished when the hollow fibers 26 expand to a thicker state. It is noted that Silvestrini does not disclose any specific structure in the hollow fibers to limit how the expansion of the device. Therefore, generally expanding the hollow fiber to have a bigger diameter will increase the overall diameter of the device, and will inherently reduce the size of any openings between two fibers because the expansion of those fibers will occupy part of the openings.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., incubating a hydrogel in a low pH for 70 hrs., etc.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Note that claim 95 merely requires a hydrogel that changes from its first state of protonation to a second state of protonation. This characteristic is well known in the art, as taught by Petka et al.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/  
Primary Examiner, Art Unit 3773